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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,188	06/21/2007	Eugen Kolossov	2590.0040002/EJH/UWJ	7273

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EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
10/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,188	KOLOSSOV ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,17,19-32,45-52 and 54-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-7,13,17,19-29,31,45,49-52,54-65,67,69 and 70* is/are allowed.

6)☒ Claim(s) *8,10,11,30,32,46,66 and 68* is/are rejected.

7)☒ Claim(s) *9,47 and 48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-24-10 has been entered.

Applicant's amendment filed 7-26-10 has been entered. Claims 1, 5, 6, 45, 49 and 50 have been amended. Claims 12, 14-16, 18, 33-44 and 53 have been canceled. Claims 1-11, 13, 17, 19-32, 45-52 and 54-70 are pending and under consideration.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 8 recites the limitation "step (a)" in line 2. There is insufficient antecedent basis for this limitation in the claim.

4. Claim 10 recites the limitation "step (b)" in line 2. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 11 recites the limitation "step (b)" in line 2. There is insufficient antecedent basis for this limitation in the claim.

6. Claim 46 recites the limitation "step (a)" in line 2. There is insufficient antecedent basis for this limitation in the claim.

7. Claims 30 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "selected from promoters of alpha-myosin heavy chain (alpha-MNC) or ventricular myosin light chain 2 (MLC2v)" in claims 30 and 66 is vague and renders the claims indefinite. It is unclear whether it is selected from promoters of alpha-myosin heavy chain (alpha-MNC) only or selected from the promoters of alpha-myosin heavy chain (alpha-MNC) and ventricular myosin light chain 2 (MLC2v). Changing the phrase to "selected from the group consisting of the promoters of alpha-myosin heavy chain (alpha-MNC) and ventricular myosin light chain 2 (MLC2v)" would be remedial.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 32 and 68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for generation of cardiomyocytes from EBs obtained from embryonic stem cells, does not reasonably provide enablement for generation of cardiomyocytes from various pluripotent cells other than embryonic stem cells and generation of tissue of cardiomyocytes from various pluripotent cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considered whether the claimed invention provides sufficient guidance to make and use the claimed invention, if not, whether an artisan would have required undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirement, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue" (In re Wands, 858 F.2d at 737, 8 USPQ2d 1400, 1404 (Fed. Cir.1988)).

Furthermore, the USPTO does not have laboratory facilities to test if an invention with function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raises and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

Claims 32 and 68 read on a cardiomyocytes or tissue of cardiomyocytes obtained from the embryoid body (EB).

The specification discloses formation of EB from embryonic stem cells, differentiation of EBs into cells that express GFP under the control of alpha-MHC promoter in vitro (e.g. Example 2). The claims encompass formation of tissue of cardiomyocytes, which includes heart. The specification fails to provide adequate guidance and evidence for the formation of any tissue of cardiomyocytes from EBs or formation of cardiomyocytes from EBs derived from various

pluripotent cells other than embryonic stem (ES) cells. Nguyen et al., 2010 (Advanced Drug Delivery Reviews xxx, p. 1-12) points out that although stem cell therapy has the potential to regenerate injured tissue but the stem cells must differentiate into the target cells and engraft. "To fully characterize these cells, evaluation of cell morphology, lineage specific markers, cell specific function, and gene expression must be performed. To monitor survival and engraftment, cell fate imaging is vital. Only then can organ specific function be evaluated to determine the effectiveness of therapy" (e.g. abstract). The specification fails to provide evidence for whether the EBs can differentiate into tissue of cardiomyocytes, such as heart. The differentiation of pluripotent cells into cardiomyocytes and tissue of cardiomyocytes require careful monitoring of the cell morphology, lineage specific markers, cell specific function and organ specific function. It was unpredictable at the time of the invention whether the EBs fromed from various pluripotent cells can differentiate into cardiomyocytes and form tissue of cardiomyocytes. There is no evidence of record that demonstrate pluripotent cells other than embryonic stem cells can differentiate into cardiomyocytes, and no evidence of record that demonstrate pluripotent cells can differentiate into tissue of cardiomyocytes via EBs. Absent specific guidance, one skilled in the art at the time of the invention would not know how to obtain cardiomyocytes from various pluripotent cells other than embryonic stem cells or how to obtain tissue of cardiomyocytes from various pluripotent cells as claimed.

For the reasons discussed above, it would have required undue experimentation for one skilled in the art at the time of the invention to practice over the full scope of the invention claimed. This is particularly true given the nature of the invention, the state of the prior art, the breadth of the claims, the amount of experimentation necessary, the level of skill which is high,

the working examples provided and scarcity of guidance in the specification, and the unpredictable nature of the art.

Conclusion

Claims 8, 10, 11, 30, 32, 46, 66 and 68 are rejected. Claims 9, 47 and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 1-7, 13, 17, 19-29, 31, 45, 49-52, 54-65, 67, 69 and 70 are in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen
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